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August 15, 2002

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

Re: Comments in Response to Notice in Federal Register, Volume 67, No. 95, page 34942, dated, Thursday, May 16, 2002

To Whom It May Concern:

The International Trademark Association (INTA) respectfully submits these comments in connection with FDA's consideration of First Amendment issues raised by its regulations, guidances, policies and practices. *See* 67 Fed. Reg. 34942 (2002).

INTA, a 124-year-old worldwide organization representing over 3,300 corporations, law firms and professional associations in 120 countries, takes positions on matters of public policy when the underlying principles and functions of trademarks or the trademark system are involved.

In these comments, INTA addresses First Amendment issues raised by (1) FDA's practice of not giving any weight to determinations by the United States Patent and Trademark Office (PTO) that two trademarks do not create a likelihood of confusion, and adopting its' own subjective standard of likelihood of confusion between trademarks in order to determine an applicant's right to use its' trademark, and (2) FDA's apparent goal of preventing innovator companies from using multiple trademarks on products containing the same active ingredient even where the trademarks themselves do not create a likelihood of confusion.

INTA assumes for purposes of these comments that a company's use of trademarks in its labeling and advertising is properly viewed as commercial speech, identifying the product the company seeks to sell and imparting important information to consumers about the product. See, e.g., Friedman v. Rogers, 440 U.S.1 (1979) (a trade name, which generally receives the same protection under the law as trademarks, "is used as part of a proposal of a commercial transaction" and is protected commercial speech under the First Amendment); McCarthy on Trademarks and Unfair Competition §30:139 at 31-221 (4th

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ed. 2001) ("[A] firm's trademark is the most important element of commercial speech which is communicated to customers".) Under current Supreme Court doctrine, regulation of commercial speech, including uses of trademarks considered to constitute commercial speech, are subject to analysis under Central Hudson Gas & Electric Corp. v. Public Service Comm'n, 447 U.S. 557 (1980).

1. *FDA practice with respect to likelihood of confusion determinations.* The First Amendment allows the government to regulate commercial speech to prevent it from being misleading or deceptive. But "mere speculation and conjecture" is insufficient; instead, FDA must demonstrate that "the harms it recites are real." *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993). Especially where another expert agency, the PTO, has already determined that use of a trademark does not create a likelihood of confusion with another trademark, FDA should be held to a stringent standard in seeking to justify a contrary determination. FDA's current practice does not meet such a standard.

Under *Central Hudson Gas & Electric Corp. v. Public Service Commission,* 447 U.S. 557, 566 (1980), the initial inquiry is whether the speech at issue concerns lawful activity and is not misleading. The selling of pharmaceuticals approved by FDA is a lawful activity. Further, by distinguishing products, trademarks for pharmaceutical products have an important purpose in providing truthful information to healthcare providers and consumers. The case law is clear that "[t]he FDA may not restrict speech based on its perception that the speech could, may or might mislead". *Washington Legal Found. v. Henny*, 56 F. Supp. 2d 81, 85 (D.P.C.1999). Rather, for the FDA to reject a trademark it must have sufficient evidence that the trademark being considered for use on a new pharmaceutical preparation is misleading.

Current FDA practice considers the potential of trademarks to mislead by using internal testing, which is the basis of FDA's opinion on the acceptability of a trademark for a particular product. In considering whether a trademark can mislead, FDA considers look-alike and sound-alike similarity to existing trademarks and non-proprietary names, as well as, whether the proposed trademark suggests claims not established for the product. The determination by FDA on these issues is based upon the opinion of a small group which considers the results of a very limited sampling of personnel within FDA. The accuracy of such limited, subjective testing to determine whether a mark is truly misleading has not been validated, and therefore, a finding that the mark is misleading is based on a perception that the mark could, may or might mislead, but does not constitute the basis required to restrict commercial speech.

Obviously, there are instances where use of a proposed mark would be misleading on its face, for example, where an existing in use mark for a specific pharmaceutical product of one company, is then proposed in its exact, or virtually exact form, by another company for a different pharmaceutical product or where the mark clearly indicates a claim for the

product not established for it. But FDA cannot substantiate that a proposed mark will mislead based upon a claim of look-alike, sound-alike possibility, where non-identical marks are judged under a limited, subjective, non-scientific, testing model. This is especially true, in instances where the proposed mark has already been reviewed by the PTO, and the mark has been registered on the Principal Register, thus, obtaining the statutory presumption of validity and of the owner's right to use the mark in commerce. The PTO is the federal agency with primary responsibility for trademark issues. The action taken by the PTO in registering a mark, and its determination that it will not likely cause confusion, should be accepted by FDA, unless it can show by the strongest of evidence that the PTO was mistaken on the issue of likelihood of confusion.

2. *FDA's apparent goal of preventing innovator companies from using multiple trademarks on products containing the same active ingredient even where the trademarks themselves do not create a likelihood of confusion.* OPDRA has indicated that it views such multiple trademarks as both "unnecessary" and potentially harmful, regardless of whether the individual trademarks themselves create a likelihood of confusion, because of its concern that multiple trademarks will increase the risk of medication errors. Accordingly, OPDRA has announced that CDER would "strongly discourage" multiple trademarks for the same company for the same active ingredient.[1] INTA submits that this policy violates the First Amendment.

When the commercial speech in question is neither unlawful or misleading, *Central Hudson* dictates that a restriction on such speech must satisfy the following criteria. Specifically, the action must (1) seek to support a substantial government interest; (2) directly advance that interest; and (3) be no more extensive than necessary to serve that interest. *Central Hudson*, 447 U.S. at 566; *see also Bd. Of Trustees of the State University of New York v. Fox*, 492 U.S. 469, 480 (1989) (interpreting final factor to mean that restriction must be "narrowly tailored to achieve the desired objective".)

Because the government undeniably has an interest in protecting the health and safety of its citizens, *see Thompson v. Western States Medical Center*, 535 U.S.____ (2002), the constitutionality of the FDA's action turns on whether it directly advances that interest and is no more extensive than necessary. The government "bears the burden of showing not merely that its [action] will advance its interest but also that it will do so to a material degree" *44 Liquormart, Inc.*, 517 U.S. at 505 (internal quotation and citation omitted). To meet this burden "mere speculation or conjecture" is insufficient and in contrast, the FDA must offer concrete proof that "the harms it recites are real and that its restriction will in fact alleviate them to a material degree" *Edenfield v. Fane*, 507 U.S. 761, 770-71

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[1] This concern does not lead CDER to prohibit the adoption of different trademarks for the same active ingredient by different companies, in the case of generic manufacturers adopting trademarks for ANDAs, but only the adoption of different trademarks for the same active ingredient by the same company.

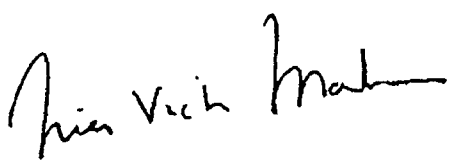
(1993). There is no evidence that the current practice of FDA in its trademark review and denial of the right to use a non-identical trademark advances its interest in protecting the public from medication errors. The rejection of the right to use is based upon non-scientific "speculation or conjecture".

There is no evidence that medication errors would be reduced by FDA denying the right to use a trademark that is not misleading. Such action by FDA does not address factors that contribute significantly to medication errors, including poor handwriting, poor auditory conditions during verbal orders, incomplete prescribing information, distractions in the pharmacy or hospital, poor lighting, inadequately trained staff, and over-worked personnel. It is not at all clear that FDA's rejection of non-misleading trademarks would achieve the government's purpose of reducing medication errors. There are alternative, less restrictive means of addressing the problem of medication errors such as attending to the significant factors mentioned above which will more likely achieve the government's goal.

Therefore, the trademark review practice of FDA does not meet the government's burden necessary for it to restrict the applicant's protected constitutional commercial free speech right to use its trademark.

Thank you for your consideration.

Sincerely,



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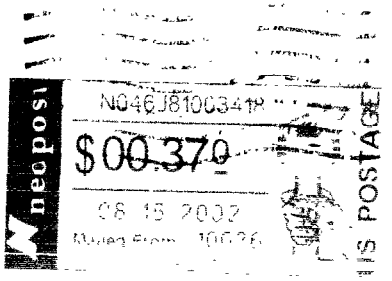

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